

K081129

## 510(k) SUMMARY

### 1. Submitter Name and Address

JUL 28 2008

SurgRx, Inc.  
101 Saginaw Drive  
Redwood City, CA 94063  
Contact: Linda Oleson  
Phone: (650) 482-2400 ext 107  
Date: 6/13/08

### 2. Device Name

Trade name: EnSeal PowerTip with EnSeal Universal

Common name: Electrosurgical open and laparoscopic instruments and accessories

Classification name: Electrosurgical Cutting and Coagulation Device and Accessories (per 21 CFR section 878.4400) and Gynecologic Electrocautery and Accessories (per 21 CFR 884.4120).

### 3. Predicate Devices

EnSeal Vessel Sealing and Hemostasis System: k031133, k043008, k050671, k061526, k062949, k063097, k070165, k070896, k072177, k072493, LigaSure Advance: k063195, Gyrus Bipolar Needle Electrode: k031079, ValleyLab ForceTriad: k051644.

### 4. Device Description

EnSeal PowerTip with EnSeal Universal. The functionality of the devices are the same as the predicate devices.

### 5. Intended Use

The EnSeal PowerTip with EnSeal Universal generator is intended for use during open or laparoscopic general and gynecologic surgery to cut and seal vessels, cut, grasp and dissect tissue and/or seal vessels during surgery. The cutting tip feature is intended for use in the dissection of tissue planes and the creation of enterotomies and gastrotomies. The SurgRx EnSeal PowerTip with EnSeal Universal has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this system for these procedures.

### 6. Technological Characteristics

The EnSeal PowerTip with EnSeal Universal generator is the same as the predicate devices in that they are electrosurgical instruments with monopolar and bipolar capabilities.

### 7. Performance Data

Preclinical laboratory (bench) and performance tests were executed to ensure the devices function as intended and meet design specifications.

### 8. Conclusions

Based on performance testing and functional similarities to the predicate devices, we believe the EnSeal PowerTip with EnSeal Universal generator devices are safe and effective and substantially equivalent to the predicate devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SurgRX, Inc.  
% Ms. Linda Oleson  
Director of Clinical & Regulatory Affairs  
Consultant  
101 Sawinaw Drive  
Redwood City, California 94063

**JUL 28 2008**

Re: K081129

Trade/Device Name: EnSeal PowerTip with EnSeal Universal  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: II  
Product Code: GEI  
Dated: June 13, 2008  
Received: June 17, 2008

Dear Ms. Oleson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Linda Oleson

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Statement

Applicant: SurgRx, Inc.

510(k) number (if known): K081129

Device Name: EnSeal PowerTip with EnSeal Universal

Indications for Use:

The EnSeal PowerTip is an electrosurgical instrument for use with the EnSeal Universal electrosurgical generator. It is intended for use during open or laparoscopic, general and gynecologic surgery to cut and seal vessels, cut, grasp and dissect tissue during surgery.

Indications for use include open and laparoscopic general and gynecological surgical procedures (including urologic, thoracic, plastic and reconstructive, bowel resections, hysterectomies, cholecystectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomies), or any procedure where vessel ligation (cutting and sealing), tissue grasping and dissection is performed. The devices can be used on vessels up to (and including) 7 mm and bundles as large as will fit in the jaws of the instruments.

The cutting tip feature is intended for use in the dissection of tissue planes and the creation of enterotomies and gastrotomies.

The EnSeal PowerTip has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this system for these procedures.

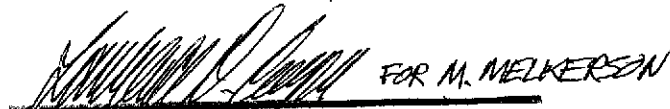
Prescription Use X  
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

 FOR M. MELKERSEN

**(Division Sign-Off)**  
**Division of General, Restorative,**  
**and Neurological Devices**

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